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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER
CROUCH, J.

ART UNIT
1819

PAPER NUMBER
34

DATE MAILED: 01/13/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on DC 20, 1992

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1835 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4, 6-9, 11, 12, 14 and 16-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4, 6-9, 11, 12, 14 and 16-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on April 30, 1996 has been entered.

The declaration filed December 20, 1996 by Kenneth R. Bondioli has been considered, but is not persuasive.

Claim 16 filed with the amendment of January 29, 1996 was withdrawn from restriction by original presentation in the office action mailed April 30, 1996. However, the examiner has reconsidered and will examine this claim with pending claims 1-4,6-9,11,12,14 and 17-24.

Claims 2,7, 12,14,17,20,21 and 24 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic mice, rats, rabbits, pigs, sheep and goats, does not reasonably provide enablement for transgenic cows. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's species claim to transgenic cows for the production of any protein in the mammary gland for eventual isolation from the cow's milk is not enabled by the disclosure, nor are there sufficient teachings in the art for the production of such a transgenic cow that the specification does not have to provide guidance for this species. The production of transgenic cows, at least by a review of the art at the time of filing, appears to be problematic as at the time

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of filing there are no reports of the production of transgenic cows that produce recoverable amounts of protein routinely from their milk. At the time of filing, the art recognized the technical difficulty in producing transgenic livestock, of which cow is a member (Henninghausen, page 7, col. 2, parag. 1, lines 1-3). In referring to factor VIII, Henninghausen also teaches that transgenic rabbits would be animal of choice to produce sufficient factor VIII (Henninghausen, page 7, col. 2, line 8-11). Thus at the time of filing, transgenic cows as being a readily available and routinely produced bioreactor for protein production was not accepted by the art. As applicant is well aware at this juncture in prosecution, the claims for their full breadth must be enabled for the time of filing, and not the time of examination. Therefore, as the artisan can not rely on the art for direction in the production of transgenic cows making any protein, it is necessary that the specification provide such direction.

Applicant has supplied a declaration by Kenneth R. Bondioli where the declarant described his personal experience in transgenic cattle projects prior to and at the time of filing the instant application. Declarant indicates that in 1991 live transgenic cattle were produced by methods which involved the centrifugation of cattle zygote to visualize the pronuclei as well as other methods detailed in journal articles supplied as exhibits B-E. These arguments and disclosures are not persuasive as there is no indication that the transgenic cattle produced at or prior to the filing date produced isolatable quantities of a protein in their milk and that such a cattle would have been predictably produced given such knowledge. While the mere production of cattle which contain an integrated transgene at birth is a necessary first step, this event does

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not teach that it would be predictable to produce a transgenic cow that expresses any and all transgenes encoding a protein in recoverable quantities. Furthermore, each of declarant's exhibits indicates that for transgenic cows, microinjected zygotes were fertilized in vitro for 7 days or to the morulae/blastocyst stage (Biery et al (Exhibit B), parag. 1, lines 16-19; Bondioli et al (Exhibit C), page 267, parag. 22.1.4; Massey (Exhibit D), page 205, parag. 1, lines 3-4 and Hill et al (Exhibit E), lines 12-13). Either one of these conditions would indicated that in the production of transgenic cows, the implanted embryos was at 32-124 cell stage, whereas the specification teaches the direct implantation of microinjected zygotes into the mouse or pig. As all of the art provided teaches the in vitro maturation of cow or cattle microinjected zygotes, this appears to be necessary for production of transgenic cows. Therefore, the exhibits supplied by declarant do not support the disclosure, but rather supply teaching not disclosed but appear necessary. For these reasons, the lack of recoverable or even detectable protein production in the milk of the transgenic cows in the exhibits and the production of transgenic cows by a method materially different from that disclosed in the specification, the declaration by Bondioli is not persuasive.

Claims 2,4,7,9,11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 2 and 7 are vague and indefinite in that "portions of " is not clearly stated. It is not clear which portions or how large the portions need to be. The reader would not know the metes and bounds of the invention claimed as written.

Claims 4,9 and 11 contain the term "consisting essentially of", which is proper only in a composition. Further, the specification does provide a clear definition of "essentially".

Claim 12 is confusing there is not antecedent basis within the claim for "said protein" or "said peptide".

The claims are free of the prior art. At the time of the instant invention, the art did not recognize or suggest the production of protein C in the milk of transgenic non-human mammals.

Claims 1,3,6,8,16,19,22 and 23 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Deborah Crouch

Dr. D. Crouch
January 9, 1997

DEBORAH CROUCH
PATENT EXAMINER
GROUP 1800